

R E M A R K S

Claims 1, 3, 4, 6, 11, and 14-26 are pending. No amendments have been made by way of the present submission; therefore, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 3, 4, 6, 11 and 14-26 under 35 U.S.C. § 103(a) as being obvious over Posti et al., U.S. Patent No. 5,525,354 (hereinafter referred to as Posti '354) in view of WO 96/21429 (hereinafter referred to as WO '429) and Remington's Pharmaceutical Sciences. Applicants respectfully traverse this rejection.

This is substantially the same rejection presented by the Examiner during prosecution and as affirmed by the Board of Appeals. However, the present claims differ from the claims, which were reviewed by the Board of Appeals.

Reviewing the relevant independent claims, Applicants draw the Examiner's attention to important limitations, which were added to the claims in the Amendment filed December 1, 2003.

Claim 1 now specifically states that the tablet form "is not coated with a film forming agent." Claim 11 requires that the pharmaceutical preparation "is not coated with a film forming agent." Claim 23 uses closed "consisting of" language and claim 26 states that "said tablet form is not coated with an enteric coating."

The Examiner has responded to these claim limitations by asserting that the Board had stated "The presence or absence of an enteric coating fails to distinguish the claimed subject matter from the disclosure of the references on record." However, the Board's statement, as quoted by the Examiner at page 6 of the outstanding Office Action, was based upon the claims that were appealed. These claims did not include the limitations as discussed above. In particular, the claims did not specifically exclude the coating of a film forming agent or an enteric coating.

Accordingly, Applicants submit that the Examiner is quoting the Board's statement out of context. In fact, a review of Posti '354 reveals that Posti '354 specifically desires an enteric coating, thus, the motivation to one of skill in the art would be to use an enteric coating, not exclude one (as claimed). In particular, the Examiner's attention is directed to column 5, lines 1-8 of Posti '354 wherein enteric-coated tablets are disclosed as having twice the bioavailability of other tablets.

The Examiner's attention is also directed to Posti '354 at column 1, lines 40-57 where it is disclosed that the preparation of the drug delivery form is "enteric coated with a film which dissolves at a pH of from 5 to 7.2." In fact, at column 1, line 40 of Posti '354, it is disclosed that an objective of the invention is achieved only if the enteric coating is present.

Neither WO '429 nor Remington's Pharmaceutical Sciences cure this deficiency. For instance, WO '429 discloses at page 26, lines 9-20 that particular types of enteric coating materials, which are the same as the materials discussed by Posti '354, may be employed. Also, Remington's Pharmaceutical Sciences does not provide any relevant disclosure on this issue.

In summary, Applicants respectfully submit that no motivation exists to modify Posti '354 as discussed by the Examiner. In particular, no motivation exists to remove the coating on the tablet of Posti '354. The Examiner has pointed to an uncoated tablet of Post '354 (see column 3, line 60 to column 4, line 10. However, the uncoated tablet of Posti '354 is a comparative example, which does not contain microcrystalline cellulose and is therefore not relevant.

Applicants also wish to advise the Examiner that although in the preparation of the coated tablet of Posti '354, an "uncoated"

tablet must first be formed, there is no motivation to modify such an intermediate "uncoated" tablet. Certain U.S. case law exists indicating that one of ordinary skill in the art would not be motivated to take an intermediate compound (e.g., an uncoated tablet of Posti '354) and then modify that intermediate. Likewise, one of ordinary skill in the art would not take the uncoated tablet of Posti '354 and then substitute the microcrystalline cellulose with silicified microcrystalline cellulose. Homologous intermediates of the prior art which would not obviously have properties in common with the claimed compounds does not render the latter obvious if there is no motivation to interrupt the prior art synthesis to determine the properties possessed by the intermediates. In re Lalu et al., 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984).

Accordingly, Applicants submit that there is no motivation to remove the enteric coating of Posti '354 and replace the microcrystalline cellulose with the silicified microcrystalline cellulose of WO '429. Therefore, the present claims are distinct from the cited art. Whether taken alone or in combination, the cited art fails to suggest or disclose the presently claimed subject matter. Accordingly, no *prima facie* case of obviousness exists. Reconsideration and withdrawal of the outstanding rejection are therefore requested.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.


Appl. No.:09/486,971

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee of \$110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fee required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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